RESPONSE TO OFFICE ACTION

A. Status of the Specification

The specification has been amended to correct deficiencies relating to information for the deposit of seed for the claimed inbred. The objection to the specification should now be moot.

B. Status of the Claims

Claims 1-28 were filed with the original application. Claim 24 has been cancelled herein. The amendments insert the accession number for a deposit of seed of variety 5750. Claims 1-23 and 25-28 are now pending and presented for reconsideration.

C. Rejection of Claims Under 35 U.S.C. §112, First Paragraph - Enablement

(1) The Action rejects claims 1-31 under 35 U.S.C. §112, first paragraph, for lack of a seed deposit.

In response, Applicant notes that a deposit of 2,500 seeds of the variety 5750 was made with the ATCC. The deposit was made in accordance with the terms and provisions of 37 C.F.R. §1.808 relating to deposits of microorganisms. The deposit was made for a term of at least thirty years or at least five years after the most recent request for furnishing of a sample of the deposit is received by the depository or for the effective life of the patent, whichever is longer. A declaration certifying that the deposit meets the criteria set forth in 37 C.F.R. §1.801-1.809 is attached hereto under **Appendix A**. The specification has also been amended to include the accession number of the deposit and the date of deposit.

(2) The Action rejects claim 9 and 22-28 as not being enabled. With regard to claim 9, this is directed to the plant of claim 8 comprising a factor conferring male sterility. Claim 8 has only been rejected with regard to a deposit of seed, and this rejection is now believed moot in view of the response above. The rejection is thus apparently made with regard to the ability to introduce a factor conferring male sterility. However, introduction of male sterility is both well known and described in the specification. Genes for male sterility are described, for example, in U.S. Patent No. 3,861,709, U.S. Patent No. 3,710,511, U.S. Patent No. 4,654,465, U.S. Patent No 5,625,132, and U.S. Patent No. 4,727,219, U.S. Patent No. 5,530,191; U.S. Patent No. 5,689,041; U.S. Patent No. 5,741,684; and U.S. Patent No. 5,684,242; each of the disclosures of which were specifically incorporated by reference in their entirety in the application. Applicants therefore respectfully submit that male sterile plants are fully enabled.

With regard to claims 22-24, these are directed to hybrid plants having corn plant 5750 as one parent. Applicants note that the claimed hybrid plants are made anytime corn plant 5750 is crossed to a second plant. The basis for the rejection is thus not understood. Certainly it would be well within the capabilities of one of skill in the art to cross corn plant 5750 with *any* second plant.

In an attempt to support the rejection, the Action cites several references alleged to show the difficulty of making male sterile or single locus converted plants. However, no basis has been given to show that these references have any relevance to *corn* plants. Hunsperger deals with petunias; Kraft with sugar beets and Eshed with Tomatoes. No allegation has been made that the references refer to corn plants. The relevance of the

references to the claimed invention has therefore not been established as is specifically required to establish a *prima facie* case of non-enablement.

The Action disregards Applicants example of a conversion that has been made with a proprietary corn variety. The breeding history of the conversion that was made is given. In the breeding history, seven backcrosses are described. No steps are left out and no basis has been provided to demonstrate why this example does not demonstrate enablement for the instant variety. In view of Applicants example, the detailed teaching in the specification and the failure to provide any basis to doubt the enablement of the claims, removal of the rejection is respectfully requested.

In light of the foregoing, Applicant respectfully requests removal of the rejection under 35 U.S.C. §112, first paragraph.

D. Rejection of Claims Under 35 U.S.C. §112, First Paragraph – Written Description

The Action rejects claims 9 and 22-28 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to convey that Applicants were in possession of the claimed invention. Applicants traverse as the claimed subject matter is fully described as set forth below.

(1) Male sterile and single locus converted plants of corn variety 5750 in claims 9 and 25-28 have been fully described

The Action rejects claim 9, which is directed to the plant of claim 8 further comprising a factor conferring male sterility, and claims 25-28, which are directed to a single locus conversion of corn plant 5750. In particular, the Action has alleged that: (1) the characteristics of the claimed plants are unpredictable and/or not described, (2) the claims encompass genes that have yet to be discovered, and (3) the sequences and/or

sources for the numerous examples of single locus traits disclosed in the application have not been described.

a. The claimed subject matter is not unpredictable

With regard to the first point made by the Action, it is noted that claim 9 depends from claim 8. Claim 9 thus specifies all of the limitations of claim 8, but further specifies that the plant comprises a factor conferring male sterility. Nothing is therefore unpredictable about the characteristics of this plant; the characteristics are expressly set forth in the claim. With respect to claims 25-28, these are directed to a corn plant of variety 5750, e.g., the corn plant of claim 4, comprising a single locus conversion. A "single locus converted (conversion) plant" is defined at page 23, lines 6-12 of the specification as follows:

> [p]lants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus transferred into the inbred *via* the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus).

Therefore, the claimed plants comprising a single locus conversion possess "essentially all of the desired morphological and physiological characteristics of [the single gene converted plant]". The Action's comments with regard to various allegedly unknown characteristics are thus outside the scope of the claims. With regard to the claimed subject matter, Applicants have more than adequately described such a plant that comprises essentially all of the desired morphological and physiological characteristics of corn plant 5750 by way of the description and deposit of 5750 alone, not to mention other description provided. To hold otherwise would be to limit Applicants to that subject

matter described *ipsis verbis* in the specification. This position is expressly contradictory to Federal Circuit precedent. *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (stating that the written description requirement does not require an applicant to "describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (citations omitted)) .

b. The rejection has been applied with respect to unclaimed subject matter

With respect to the Action's allegation that the claims encompass genes that have yet to be discovered, it is noted that Applicants ***do not claim undiscovered genes***. The claimed subject matter is the corn variety 5750 comprising a single locus conversion. Any single locus conversion may be introduced into corn variety 5750 to produce the claimed single locus conversion. The fact that a given gene could be isolated in the future and introduced as a single locus conversion is irrelevant – the new gene is not claimed *per se*, a single locus conversion of corn plant 5750 is claimed. Under the reasoning of the Action, essentially any claim could be read to encompass subject matter yet to be invented and therefore not be described. A claim to a corn plant transformed with a particular gene would be invalid because it would encompass corn varieties yet to be discovered. A claim to a given gene operably linked to a regulatory element would be invalid because as yet to be isolated regulatory elements would be encompassed. Nearly any biotechnological invention could be viewed this way applying the Action's reasoning. However, it is not any given single locus that is claimed, it is a corn plant of corn variety 5750 which comprises a single locus that has been claimed. The claimed subject matter is thus fully described.

c. Applicants have disclosed numerous single locus traits and these traits were well known to those of skill in the art when the application was filed

The Action alleges that the traits recited in the application and referred to in Applicants previous response to office action have not been shown to have been known in the art. The Action has therefore invited Applicants to amend the claims to recite individual examples of single locus traits. However, Applicants' previous evidence submitted in the prior response to office action showed numerous single locus traits.

With regard to male sterility, the specification gives examples of genes conferring male sterility, as well as restorers of male-sterility for plant breeding purposes, by way of U.S. Patent No. 3,861,709, U.S. Patent No. 3,710,511, U.S. Patent No. 4,654,465, U.S. Patent No 5,625,132, and U.S. Patent No. 4,727,219, U.S. Patent No. 5,530,191; U.S. Patent No. 5,689,041; U.S. Patent No. 5,741,684; and U.S. Patent No. 5,684,242; each of the disclosures of which were specifically incorporated by reference in their entirety in the application. These examples clearly demonstrate that factors conferring male sterility were well known in the art.

The single locus traits are also described in the specification by way of PCT Application Publ. WO 95/06128, which was specifically incorporated by reference at page 31 of the specification. Examples of some of the single locus traits described in WO 95/06128, including any associated phenotype and publication reference given, are the following:

the uidA gene from *E. Coli* encoding β-glucuronidase (GUS) (cells expressing *uidA* produce a blue color when given the appropriate substrate, Jefferson, R.A. 1987. *Plant Mol. Biol. Rep* 5: 387-405); the *bar* gene from *Streptomyces hygroscopicus* encoding phosphinothricin acetyltransferase (PAT) (cells expressing PAT are resistant to the herbicide Basta, White, J., Chang, S.-Y.P., Bibb, M.J., and Bibb, M.J. 1990. *Nucl. Ac. Research* 18: 1062); the *lux* gene from firefly encoding luciferase (cells expressing *lux* emit light under appropriate assay conditions, deWet, J.R., Wood, K.V., DeLuca, M.,

Helinski, D.R., Subramani, S. 1987. *Mol. Cell. Biol.* 7: 725-737); the *dhfr* gene from mouse encoding dihydrofolate reductase (DHFR) (cells expressing *dhfr* are resistant to methotrexate; Eichholtz, D.A., Rogers, S.G., Horsch, R.B., Klee, H.J., Hayford, M., Hoffman, N.L., Bradford, S.B., Fink, C., Flick, J., O'Connell, K.M., Frayley, R.T. 1987. *Somatic Cell Mol. Genet.* 13: 67-76); the *neo* gene from *E.Coli* encoding aminoglycoside phosphotransferase (APH) (cells expressing *neo* are resistant to the aminoglycoside antibiotics; Beck, E., Ludwig, G., Auerswald, E.A., Reiss, B., Schaller, H. 1982. *Gene* 19: 327-336); the *amp* gene from *E. Coli* encoding β-lactamase (cells expressing β-lactamase produce a chromogenic compound when given the appropriate substrate; Sutcliffe, J.G. 1978. *Proc. Nat. Acad. Sci.* USA 75: 3737-3741); the *xylE* gene from *Ps. putida* encoding catechol dihydroxygenase (cells expressing *xylE* produce a chromogenic compound when given the appropriate substrate; Zukowsky *et al.* 1983. *Proc. Nat. Acad. Sci.* USA 80: 1101-1105); the R,C1 and B genes from maize encode proteins that regulate anthocyanin biosynthesis in maize (Goff, S., Klein, T., Ruth, B., Fromm, M., Cone, K., Radicella, J., Chandler, V. 1990. *EMBO J.:* 2517-2522); the ALS gene from *Zea mays* encoding acetolactate synthase and mutated to confer resistance to sulfonylurea herbicides (cells expressing ALS are resistant to the herbicide; Gleen. Yang, L.Y., Gross, P.R., Chen, C.H., Lissis, M. 1992. *Plant Molecular Biology* 18: 1185-1187); the proteinase inhibitor II gene from potato and tomato (plants expressing the proteinase inhibitor II gene show increased resistance to insects; potato - Graham, J.S., Hall, G., Pearce, G., Ryan, C.A. 1986 *Mol. Cell. Biol.* 2: 1044-1051; tomato - Pearce, G., Strydom, D., Johnson, S., Ryan, C.A. 1991. *Science* 253: 895-898); the *Bt* gene from *Bacillus thuringensis* berliner 1715 encoding a protein that is toxic to insects (this gene is the coding sequence of *Bt* 884 modified in two regions for improved expression in plants; Vaeck, M., Reynaerts, A., Hofte, H., Jansens, S., DeBeuckeleer, M., Dean, C., Aeabeau, M., Van Montagu, M., and Leemans, J. 1987. *Nature* 328: 33-37); the *bxn* gene from *Klebsiella ozaeneae* encoding a nitrilase enzyme specific for the herbicide bromoxynil (cells expressing this gene are resistant to the herbicide bromoxynil; Stalker, D.m., McBride, K.E., and Malyj, L. *Science* 242: 419-422, 1988); the WGA-A gene encoding wheat germ agglutinin (expression of the WGA-A gene confers resistance to insects; Smith, J.J., Raikhel, N.V. 1989. *Plant Mol. Biology* 13: 601-603); the *dapA* gene from *E. coli* encoding dihydrodipicolinate synthase (expression of this gene in plant cells produces increased levels of free lysine; Richaud, F., Richaud, C., Rafet, P. and Patte, J.C. 1986. *J. Bacteriol.* 166: 297-300); the *Z10* gene encoding a 10kd zein storage protein from maize (expression of this gene in cells alters the quantities of 10kD Zein in the cells; Kirihara, J.A., Hunsperger, J.P., Mahoney, W.C., and Messing, J. 1988. *Mol. Gen. Genet.* 211: 477-484); the Bt gene cloned from *Bacillus thuringensis* Kurstaki encoding a protein that is toxic to insects (the gene is the coding sequence of the cry IA(c) gene modified for improved expression in plants - plants expressing this gene are resistant to insects; Höfte, H. and Whiteley, H.R., 1989. *Microbiological Reviews.* 53: 242-255); the ALS gene from *Arabidopsis thaliana* encoding a sulfonylurea herbicide resistant acetolactate synthase enzyme (cells expressing this gene are resistant to the herbicide Gleen. Haughn, G.W., Smith, J., Mazur, B., and Somerville, C. 1988. *Mol. Gen. Genet.* 211: 266-271); the *dehl* gene from *Pseudomonas putida* encoding a dehalogenase enzyme (cells expressing this gene are resistant to the herbicide Dalapon; Buchanan-Wollaston, V., Snape, A., and Cannon,

F. 1992. *Plant Cell Reports* 11: 627-631); the hygromycin phosphotransferase II gene from *E. coli* (expression of this gene in cells produces resistance to the antibiotic hygromycin. Waldron, C., Murphy, E.B., Roberts, J.L., Gustafson, G.D., Armour, S.L., and Malcolm, S.K. *Plant Molecular Biology* 5: 103-108, 1985); the *mtlD* gene cloned from *E. coli* (the gene encodes the enzyme mannitol-1-phosphate dehydrogenase; Lee and Saier, 1983. *J. of Bacteriol.* 153:685); the HVA-1 gene encoding a Late Embryogenesis Abundant (LEA) protein (the gene was isolated from barley; Dure, L., Crouch, M., Harada, J., Ho, T.-H. D. Mundy, J., Quatrano, R, Thomas, T, and Sung, R., *Plant Molecular Biology* 12: 475-486.

The foregoing represent just some of the single locus coding sequences that were known as of March 2, 1995; ***nearly six years prior*** to the filing of the instant application. More than 25 regulatory elements were also described therein, as were numerous transformation vectors comprising combinations of these elements. Applicants could describe many more examples of single locus traits that were well known as of the filing date, and would be glad to do so should the Examiner find it useful. It thus goes without saying that single locus traits were more than well known to those of skill in the art as of the filing date and were fully described in the specification.

Techniques for the introduction of single locus traits by genetic transformation were further well known to those of skill in the art. Some of the transformation methods for corn that were well known as of the filing date and cited in the specification include the following: electroporation (U.S. Patent No. 5,384,253), microprojectile bombardment (U.S. Patent No. 5,550,318; U.S. Patent No. 5,736,369, U.S. Patent No. 5,538,880; and PCT Publication WO 95/06128), *Agrobacterium*-mediated transformation (U.S. Patent No. 5,591,616 and E.P. Publication EP672752), direct DNA uptake transformation of protoplasts (Omirulleh *et al.*, 1993) and silicon carbide fiber-mediated transformation (U.S. Patent No. 5,302,532 and U.S. Patent No. 5,464,765). Introduction of such traits by conventional breeding was also known. In fact, this is one of the most fundamental

procedures in agricultural science, and it has not been alleged that this has not been described.

Applicants have therefore shown possession of the claimed single locus conversions and male sterile plants. Both large numbers of single locus traits and the associated phenotypes were well known to those of skill in the art. The specification itself defines a single locus converted plant as comprising essentially all of the desired morphological and physiological characteristics of the starting non-converted plant, *e.g.*, 5750. Well more than an adequate number of examples have been provided and were known in the art to satisfy written description. The state of the art must be considered in the written description determination. As such, Applicants respectfully request removal of the rejection.

(2) Hybrid plants and seeds recited in claims 22-23 have been fully described

Rejected claims 22-23 are directed to hybrid plants and seeds produced with corn plant 5750 as one parent. With regard to claim 24, this has been cancelled herein as duplicative of the claim from which it depended. Applicants have fully described the claimed subject matter in compliance with the written description requirement of 35 U.S.C. §112, first paragraph. As set forth in the breeding history at page 26 of the specification, corn plant 5750 is an inbred corn plant. All of the claimed hybrid plants having 5750 as a parent will therefore contain a copy of the same genome as corn plant 5750. That is, because 5750 is an inbred corn plant, hybrid corn plants derived therefrom will have as half of their genetic material the same genetic contribution of corn plant 5750, save the possibility of the rare spontaneous mutation or undetected segregating locus. This entire genetic contribution of corn plant 5750 is described in the specification

by way of the deposit of seed of corn plant 5750 with the ATCC. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002) (holding that a biological deposit constitutes a written description of the deposited material under 35 U.S.C. §112, first paragraph). This represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishing them from other plants in full compliance with the written description requirement.

The Federal Circuit has noted that such shared identifiable structural features are important to the written description requirement. *The Regents of The University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) (noting that a name alone does not satisfy the written description requirement where "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, *as one can do with a fully described genus, visualize or recognize the identity of the members of the genus*" (emphasis added)). Here, all of the members of the claimed genus of hybrids having 5750 as one parent share the structural feature of having the genetic complement of 5750. One of skill in the art could thus readily identify the members of the genus. The written description requirement has, therefore, been fully complied with.

As set forth above, the claimed F1 hybrid plants having 5750 as one parent will share the genetic complement received from 5750. This is readily identifiable by genetic marker analysis, as shown in Tables 6 and 8 of the specification. There shown is the SSR genetic marker profile of corn variety 5750, as well as an the exemplary hybrid plant designated 9900676 that was made using 5750 as one parent. As can be seen, hybrid corn plant 9900676 has the SSR genetic marker profile of 5750, and also includes the

genetic markers from the second parent plant used to make the hybrid. The same will be true for any other hybrid plant having 5750 as one parent, save for an occasional difference at a locus due to spontaneous genetic rearrangements, which occur at statistically insignificant frequencies in essentially all organisms.

The second plant that is used to make the claimed hybrid plants is irrelevant, as a hybrid will be produced any time corn plant 5750 is crossed with a second plant. That is, any second plant capable of reproduction may be used to make the hybrid plant. Applicants cannot therefore be said to lack written description for the second genetic complement. This is particularly so given that hundreds or even thousands of different inbred corn lines were well known to those of skill in the art prior to the filing of the instant application, each of which could be crossed to make a hybrid plant within the scope of the claims. This is evidenced by a review of the U.S.P.T.O. patent data website, which reveals utility patents issued on hundreds of different corn varieties. For example, a search of patents including "inbred corn line" in the title reveals more than 195 patents issued for corn varieties prior to the filing date of the current application; and a search for patents having "inbred maize line" in the title reveals more than 120 patents issued prior to the filing date. Any one of these corn plants, or the many hundreds or thousands of other maize plants that were known at the time the application was filed, could be used to produce an F1 hybrid plant having corn variety 5750 as one parent, and each of these would share the genetic complement of 5750.

Written description must be reviewed from the perspective of one of skill in the art at the time the application is filed. *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 863 (Fed. Cir. 1993). The specification need not disclose what is well-known to those

skilled in the art and preferably omits what is well-known and already available to the public. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). As *any* second plant may be used to produce the claimed hybrid plants and such plants were well known to those of skill in the art, applicants cannot be said to have not been in possession of the second parent plant. The claimed hybrid corn plants have therefore been described in compliance with 35 U.S.C. §112, first paragraph.

The law makes no distinctions regarding the manner in which applicants choose to describe claimed compositions. Rather, an applicant must merely describe the claimed subject matter by "whatever characteristics sufficiently distinguish it." *Amgen v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). Here, Applicants have described the genetic complement of parent plant 5750 that will be comprised in the claimed hybrid plants. This has been achieved using the SSR and isozyme genetic marker profiles given in tables 6-9 of the specification. Indeed, applicants describe the entire genetic complement of parent plant 5750 by way of a seed deposit made with the ATCC. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002). As such, any of the many well known marker systems may be used to readily detect and identify any of the claimed hybrids produced having variety 5750 as one parent.

Further description of claimed hybrid plants is also provided in the specification by way of a detailed description of hybrid 9900676, which was produced with 5750 as one inbred parent. This plant is representative of hybrids produced using 5750 as one parent, each of which comprise the genetic complement of the parent corn plant as set forth above. Table 4 of the specification gives the performance characteristics for 9900676 and provides comparisons against another hybrid variety. In Table 5, the

morphological traits of 9900676 are given. The SSR and isozyme marker profiles for hybrid 9900676 are given in Tables 8 and 9, respectively. This information, combined with the descriptions of 5750 in the specification and the shared structure among hybrids having corn plant 5750 as a parent, is more than adequate to describe the claimed subject matter.

In view of the foregoing Applicants respectfully request the removal of the rejection.

E. Rejection of Claims Under 35 U.S.C. §112, Second Paragraph

The Action rejects claims 9 and 25-28 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out the subject matter which Applicants regard as the invention. In particular, it is stated that the claims are indefinite for further characterizing inbred 5750 as comprising additional genes. However, Applicants note that the claims are in proper dependent form and thus are fully definite. The claims contain a reference to the claim from which they depends, contain a further limitation of the subject matter claimed in the main claim, and incorporate all elements of the claim from which they depend. The claims merely specify an additional added element. The claims are therefore fully definite and in compliance with the statutes.

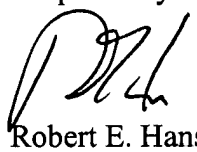
In view of the foregoing, Applicants respectfully request removal of the rejection.

F. Conclusion

This is submitted to be a complete response to the referenced Office Action. In conclusion, Applicant submits that, in light of the foregoing remarks, the present case is in condition for allowance and such favorable action is respectfully requested.

The Examiner is invited to contact the undersigned at (512)536-3085 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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